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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,877	01/12/2001	Stephen W. Noble JR.	P04808US0 PHI 1319	2539

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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
1638	7

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/759,877	NOBLE, STEPHEN W.
	Examiner David H Kruse	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 March 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-8,20,33 and 42-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 1-7,20,33,52 and 54 is/are allowed.
- 6) Claim(s) 8,42-44,46-50 and 55-62 is/are rejected.
- 7) Claim(s) 45,51 and 53 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendment filed 27 March 2003.
2. Claims 9-19, 21-32 and 34-41 have been cancelled as indicated and new claims 42-62 have been added as requested.
3. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or arguments.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

5. Claims 51 and 53 are objected to under 37 CFR § 1.75 as being a substantial duplicate of claims 20 and 33, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).
6. Claims 43-45 and 48-50 objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 43-45 are dependent upon claim 42 and claims 48-50 are dependent upon claim 47. The instant claims are improperly dependent because the claim upon which they depend is directed to a method and the instant claims are directed to a composition of

matter, hence the instant claims fail to further limit the method claim upon which they are dependent. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. Claim 8 remains rejected and claims 46-50 and 61 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 remains rejected for the reason of record put forth in the previous Office action, because it is unclear what the metes and bounds of "a genetic factor" are in the instant claim, and because the characterization of the male fertile plant of claim 2 as now being male sterile is contradictory. This rejection is repeated for the reason of record as set forth in the last Office action mailed 27 December 2002. Applicant's arguments filed 27 March 2003 have been fully considered but they are not persuasive. Applicant argues that support can be found on page 13 and that there are several methods of conferring male sterility (page 10, last paragraph of the Remarks). This is not found to be persuasive because mechanical methods do not change the inherent fertility of the maize plant, said methods only remove the male gametes from the plant, in addition, gametocides would not change the inherent fertility of the claimed maize plant. Only through introducing a transgene into the exemplified hybrid maize plant could one change the male fertility of the claimed maize plant.

At claim 46, the claim is directed to developing a backcross conversion 34M94 hybrid maize plant, at line 4, the claim recites "a transgenic 34M94 hybrid" wherein no method step of introducing a transgene is recited, hence it is unclear what the metes

and bounds of the claimed method are. Dependent claims are included in this rejection because they do not obviate the indefiniteness of the claim upon which they depend.

At claim 49, the phrase "a derivative thereof or a synthetic polypeptide modeled thereto" is indefinite because it is unclear what the metes and bounds of these limitations are in view of Applicant's teachings on page 46, 2nd paragraph of the specification.

At claim 61, line 4, the term "utilizing" is indefinite because it is unclear what the metes and bounds of this method step are.

8. Claims 46-50, 55 and 56 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 27 December 2002.

Applicant's arguments filed 27 March 2003 have been fully considered but they are not persuasive. The instant claims contain new matter not originally described in the application. Applicant argues that the specification need not disclose what is well known in the art and that it is well understood to one of ordinary skill in the art that double haploids are produced by doubling of a set of chromosomes from a heterologous plant to produce a completely homozygous individual (paragraph spanning pages 11-12 of the Remarks). This argument is not found to be persuasive because the instant specification does not adequately describe the claimed method comprising producing a

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double haploid maize plant. While Applicant is not required to describe a method well known in the art, in the instant case, it is unclear from the instant specification that Applicant had contemplated the claimed methods. Furthermore, insufficient basis in the specification exists for "at least about 75% genetic identity" at claim 56.

Claims 46-50 are directed to a method of developing a backcross conversion 35M94 hybrid maize plant by backcrossing a gene into at least one of the inbred parents. Applicant does not provide sufficient basis for the claimed method. In the paragraph spanning pages 3-4, ^{of the specification} Applicant describes recurrent selection breeding, but the described method produces a maize plant comprising the transferred "loci" controlling the characteristic of interest and is described as being "like" the superior parent for essentially all other genes. This description does not appear to describe the claimed method and is considered new matter.

9. Claims 8, 42-44 and 57-62 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 27 December 2002. Applicant's arguments filed 27 March 2003 have been fully considered but they are not persuasive.

Claim 8 remains inadequately described as set forth on the top of page 9 of the previous Office action. Applicant does not specifically address this rejection (see page 12, 2nd paragraph of the Remarks).

Claim 42 is directed to a method of developing a transgenic hybrid maize plant wherein one of the inbred parental lines is transformed with any transgene. In the instant case, Applicant does not adequately describe a myriad of transgenes, the inbred parents of 34M94 with any transgene, or how the myriad of transgene would affect either the inbred parent or the resulting transgenic 34M94 maize plant.

Claims 43 and 44 are directed to a transgenic maize plant comprising “a value added trait gene”, or “derivative thereof or a synthetic polypeptide modeled thereto” of an insect resistance *B. thuringiensis* polypeptide. Applicant does not adequately describe what the relative limitation “value added trait” is in relation to a maize plant or how to readily recognize “value” in a trait *per se* (page 49 of the specification). In addition, Applicant does not adequately describe a derivative or a synthetic peptide modeled thereto in relation to an insect resistance *B. thuringiensis* polypeptide.

Claims 57 and 59 are drawn to methods of using F2 plants, a multitude of undescribed plants with different collections of parental alleles at each locus, for further breeding steps. A method of using inadequately described products is itself inadequately described.

At claim 61, since “utilizing” fails to specify the number of generations or identity of second parent(s), the claim reads on a method of using an undefined product,

product of first cross of exemplified hybrid with another undescribed parent, in successive crosses.

Claims 58, 60 and 62 are directed to progeny of the exemplified 34M94 maize plant wherein the genetic complement of said exemplified maize plant has only been described by a deposit of biological material of said maize plant and the inbred parental lines of said maize plant. Because the exemplified 34M94 maize plant comprises the genetic complement of two distinct inbred parental maize lines, one of skill in the art cannot adequately describe what the genetic complement of a resulting progeny plant would be with any clarity.

10. Claims 8, 42-44, 46-50, and 55-62 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 8 remains rejected as lacking enablement as set forth in the sentence spanning pages 9-10 of the previous Office action. Applicant does not specifically address this rejection (see page 13, 1st paragraph of the Remarks).

Applicant has not adequately taught how to make and use the required transgenic parental inbred maize plant comprising any transgene in the method of claim 42. This issue has been addressed in previous Office actions.

At claims 43 and 44, Applicant does not provide guidance for how to make and use the claimed maize plant because Applicant does not provide guidance on how to

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make and use the genus of "value added trait genes" or the genus of derivatives or a synthetic peptides modeled thereto in relation to an insect resistance *B. thuringiensis* polypeptide.

Claims 46-50 are not enabled because ingestion of "a gene" to produce a backcross conversion is unpredictable, and Applicant has failed to adequately teach one of skill in the art how to use the claimed method. The nature of the art at the time of Applicant's invention was such that one of skill in the art could not reasonably predict what the product of a cross between two inbred parental plants would be without a reduction to practice. The art teaches that based on the number of segregating genes, the frequency of occurrence of any individual with a specific genotype is less than 1 in 10,000 and that even if the entire genotype of the parents has been characterized and the desired phenotype is known, only a few if any individuals having the desired genotype may be found in a large F_2 or S_0 population, and that typically the genotype of neither the parents nor the desired genotype is known in detail (see Segebart, U.S. Patent 5,304,719, in particular the paragraph spanning columns 2-3). The art also teaches that the number of genes affecting the trait of primary economic importance in maize, grain yield, has been estimated to be in the range of 10-1000 and that inbred lines which are used as parents for breeding crosses differ in the number and combination of these genes (Segebart, U.S. Patent 5,367,109, column 2, lines 60-64). Segebart ('109) also teaches that one of the largest plant breeding programs in the world does not have a sufficiently large breeding population to be able to rely upon "playing the numbers" to obtain successful research results and that plant breeders use

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their skills, experience and intuitive ability to select maize plants having the necessary qualities (column 4, 1st and 2nd paragraphs).

Claims 57-62 lack enablement because Applicant has failed to teach one of skill in the art how to make and use the myriad of F2 or successive filial generations of progeny plants obtained by self or sib pollination or by out-crossing with a different maize plant. Segebart, outlined above, teaches that one of skill in the art cannot predictably determine how the genes of a maize plant will recombine when crossed with another maize plant without a reduction to practice. In the instant case, maize plant 34M94 is a hybrid maize plant comprising the genetic makeup of two exemplified inbred parental lines. Segebart teaches that one of skill in the art cannot predictably determine how successive progeny genotypes will recombine.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Claims 1-7, 20, 33, 52 and 54 are allowed.
13. Claims 45, 51 and 53 are objected to.
14. Claims 8, 42-44, 46-50 and 55-62 are rejected.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

David H. Kruse, Ph.D.
28 May 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 1638

DAVID T. FOX